- (i) Show that a party could not have known of the need to file timely; or
- (ii) Prevented a party from filing timely.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996. Redesignated at 64 FR 66279, Nov. 24, 1999]

## § 478.24 Opportunity for a party to obtain and submit information.

- (a) Subject to the rules concerning disclosure of QIO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary, the QIO must provide an opportunity for examination of the material upon which the initial denial determination was based. The QIO may not furnish a provider, practitioner or beneficiary with—
- $\left(1\right)$  A record of the QIO deliberation; or
- (2) The identity of the QIO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their con-
- (b) The QIO may require the requester to pay a reasonable fee for the reproduction of the material requested.
- (c) The QIO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

# § 478.26 Delegation of the reconsideration function.

A QIO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a QIO subcontractor.

# § 478.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

- (a) Qualified under §476.98 of this chapter to make an initial determination
- (b) Not the individual who made the initial denial determination.
- (c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of QIO review.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68563, Nov. 15, 2012]

### §478.30 Evidence to be considered by the reconsideration reviewer.

- A reconsidered determination must be based on—
- (a) The information that led to the initial determination;
- (b) New information found in the medical records; or
- (c) Additional evidence submitted by a party.

### § 478.32 Time limits for issuance of the reconsidered determination.

- (a) Beneficiaries. If a beneficiary files a timely request for reconsideration of an initial denial determination, the QIO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—
- (1) Within three working days after the QIO receives the request for reconsideration if—
- (i) The beneficiary is still an inpatient in a hospital for the stay in question when the QIO receives the request for reconsideration; or
- (ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.
- (2) Within 10 working days after the QIO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the QIO receives the request for reconsideration.
- (3) Within 30 working days after the QIO receives the request for reconsideration if—
- (i) The initial determination concerns ambulatory or noninstitutional services;
- (ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or
- (iii) The beneficiary does not submit a request for expedited reconsideration timely.
- (b) Providers or practitioners. If the provider or practitioner files a request for reconsideration of an initial determination, the QIO must complete its reconsidered determination and send

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written notice to the provider or practitioner within 30 working days.

## §478.34 Notice of a reconsidered determination.

- (a) *Notice to parties*. A written notice of a QIO reconsidered determination must contain the following:
- (1) The basis for the reconsidered determination.
- (2) A detailed rationale for the reconsidered determination.
- (3) A statement explaining the Medicare payment consequences of the reconsidered determination.
- (4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.
- (b) Notice to payers. (1) A QIO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.
- (2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

#### §478.36 Record of reconsideration.

- (a) *QIO requirements*. A QIO must maintain the record of its reconsideration until the later of the following:
- (1) Four years after the date on the notice of the QIO's reconsidered determination.
- (2) Completion of litigation and the passage of the time period for filing all appeals.
- (b) Contents of the record. The record of the reconsideration must include:
  - (1) The initial determination.
- (2) The basis for the initial determination.
- (3) Documentation of the date of the receipt of the request for reconsideration.
- (4) The detailed basis for the reconsidered determination.

- (5) Evidence submitted by the parties.
- (6) A copy of the notice of the reconsidered determination that was provided to the parties.
- (7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.
- (c) Confidentiality. The record of a QIO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

### § 478.38 Effect of a reconsidered determination.

- A QIO reconsidered determination is binding upon all parties to the reconsideration unless—
- (a) A hearing is requested in accordance with §478.40 and a final decision rendered; or
- (b) The reconsidered determination is later reopened and revised in accordance with § 478.48.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985, as amended at 62 FR 25855, May 12, 1997; 62 FR 49938, Sept. 24, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68563, Nov. 15, 2012]

## §478.40 Beneficiary's right to a hearing.

- (a) Amount in controversy. If the amount in controversy is at least \$200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.
- (b) Subject matter. A beneficiary has a right to a hearing on the following issues:
  - (1) Reasonableness of the services.
  - (2) Medical necessity of the services.
- (3) Appropriateness of the setting in which the services were furnished.
- (c) Governing provisions. The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or